

EV 282961763 US

Express Mail No. EV 262001763 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/031,898  
Filing Date: 12/06/2000 (I.A.)  
Applicant: Kararli et al.  
Group Art Unit: unknown  
Examiner: unknown  
Title: Cyclooxygenase-2 Inhibitor Compositions Having Rapid Onset of Therapeutic Effect  
Attorney Docket: 6794S-000005/USC

PATENT  
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FEB 27 2003  
TECH CENTER 1600/2003  
#  
R. Harm  
3/19/03

Box: IDS  
Hon. Commissioner of Patents and Trademarks  
Washington, D.C. 20231

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, Applicant hereby submits an Information Disclosure Statement for consideration by the Examiner.

I. **LIST OF PATENTS, PUBLICATIONS, AND OTHER INFORMATION**

The patents, publications and other information submitted for consideration by the Office (except unpublished U.S. patent applications) are listed on Form 1449 attached hereto.

II. **COPIES**

A. X Submitted herewith is a legible copy of (i) each U.S. patent application publication and U.S. and foreign patent; (ii) each publication or that portion which caused it to be listed; (iii) for each cited pending U.S. application, the application specification including the claims, and any drawing of the application which caused it to be listed including the claims directed to that portion; and (iv) all other information or that portion which caused it to be listed.

B.     Any patents, publications or other information which are listed on Form 1449 or on the copies of PTO-892, but which are not enclosed herewith, were

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previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

U.S. Serial Number

U.S. Filing Date

C. \_\_\_\_ This is a PCT application in the entry of the National Phase in the United States. A copy of the International Search Report is attached for the Examiner's information. The documents listed on the International Search Report are listed on the attached Form-1449 for consideration by the Examiner and for listing on any patent resulting from this application. Since the International Search Report was from the US, EPO, or JPO search authorities, copies of these references should have been supplied to the USPTO under the trilateral agreement and are believed to be in the file of the above-identified application. (MPEP 1893.03(g))

III. CONCISE EXPLANATION OF THE RELEVANCE (check at least one box)

A. X Except as may be indicated below in (B), all of the patents, publications or other information are in the English language (concise explanation not required).

B. \_\_\_\_ A concise explanation of the relevance of each patent, publication or other information listed that is not in the English language is as follows (see 37 C.F.R. § 1.98(a)(3)):

1. \_\_\_\_ See the attached foreign patent office communication from a counterpart foreign application:
2. \_\_\_\_ English translations are provided for:
3. \_\_\_\_ Other:

C. \_\_\_\_ The following additional information is provided for the Examiner's consideration.

IV. CROSS REFERENCE TO RELATED APPLICATION(S)

A. \_\_\_\_ The Examiner is advised that the following co-pending application(s) contain(s) subject matter that may be related to the present application. By bringing this(these) application(s) to the Examiner's attention, Applicant(s) does(do) not waive the confidentiality provisions of 35 U.S.C. § 122.

Serial No.

Filing Date

Art Unit

V. THIS IDS IS BEING FILED UNDER

A. X 37 C.F.R. § 1.97(b): (check only one box)

1. \_\_\_\_ within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d) (37 C.F.R. § 1.97(b)(1)). No fee or certification is required.

2. \_\_\_ within three months of the date of entry of the national stage as set forth in §1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or certification is required.

3. X before the mailing of a first Office Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or certification is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the certification under 37 C.F.R. § 1.97(e) below; or, if no certification has been made, charge our deposit account a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).

4. \_\_\_ before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No fee or certification is required.

B. \_\_\_ 37 C.F.R. § 1.97(c): (check only one box)

- before the mailing date of either any Final Office Action under 37 C.F.R. § 1.113, a Notice of Allowance under 37 C.F.R. § 1.311, or an action that otherwise closes prosecution.

1. \_\_\_ No certification; therefore, a fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).

2. \_\_\_ See the certification below. No fee is required.

C. \_\_\_ 37 C.F.R. § 1.97(d):

- after the mailing date of either a Final Office Action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311, yet on or before payment of the issue fee.

1. \_\_\_ See the certification below. A fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).

VI. CERTIFICATION UNDER 37 C.F.R. § 1.97(e): (check only one box)

The undersigned hereby certifies that:

A. \_\_\_ each item of information contained in this IDS was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS (See 37 C.F.R. § 1.97(e)(1)). See further statement under 37 C.F.R. 1.704(d) below in section VII, if applicable; or

B. \_\_\_ no item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this IDS (See 37 C.F.R. § 1.97(e)(2)).

C. \_\_\_ Some of the items of information were first cited in a communication from a foreign patent office. As to this information, the undersigned hereby certifies that each item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby certifies that no item of this remaining information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this IDS.

VII. STATEMENT UNDER 37 CFR 1.704(d)

The undersigned hereby states that:

\_\_\_ each item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in 37 C.F.R. 1.56(c) more than thirty days prior to the filing of this IDS.

VIII. PAYMENT OF FEES (check only one box)

A. \_\_\_ A check in the amount of \$180.00 is enclosed for the above-identified fee.

B. \_\_\_ Please charge Deposit Account No. 08-0750 in the amount of \$180.00 for the above-indicated fee. A duplicate copy of this paper is attached.

The above references are being cited only in the interest of candor and without any admission that they constitute statutory prior art, contain matter which anticipates the invention, or which would render the same obvious, either singly or in combination, to a person of ordinary skill in the art. Furthermore, this Information Disclosure Statement shall not be construed as a representation that a search has been made.

If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition if necessary) and charge the appropriate fee to Deposit Account No. 08-0750.

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Please charge any additional fees or credit any overpayment pursuant to 37 C.F.R. § 1.16 or § 1.17 to Deposit Account No. 08-0750.

Respectfully submitted,

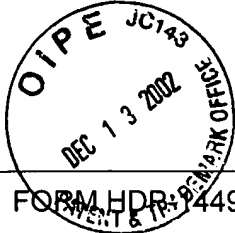
 Dated: <sup>12</sup>10/13/02

By: 

Donald R. Holland  
Reg. No. 35,197

HARNES, DICKEY & PIERCE, P.L.C.  
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FORM HDR: 1449 (Based on Form PTO-1449)

**PATENT AND TRADEMARK OFFICE  
INFORMATION DISCLOSURE CITATION**  
(Use several sheets if necessary)

Sheet 1 of 1

ATTORNEY DOCKET No.

6794S-000005/USC

SERIAL No.

10/031

APPLICANT

Kararli et al.

FILING DATE

12/06/2000 (I.A.)

GROUP

unknown

**U.S. PATENT DOCUMENTS**

Ref. Desig.	Examiner's Initials	Document Number	Date	Name	Class/ Subclass	(If appropriate) Filing Date
1.		5,518,738	05/21/1996	Eickhoff et al.	424/493	
2.		5,552,160	09/03/1996	Liversidge et al.	424/489	

**FOREIGN PATENT DOCUMENTS**

Ref. Desig.	Examiner's Initials	Document Number	Date	Country	Class/ Subclass	Translation Yes	No
3.		EC98-2761 (English Language Version)	05/06/1999	EC		X	
4.		WO 00/32189	08/06/2000	WO	A61K 31/415		X
5.		WO 99/18960	22/04/1999	WO	A61K 31/47, 45/06		X

**OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)**

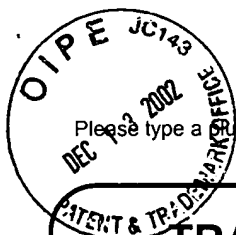
Ref. Desig.	Examiner's Initials	
6.		EP Communication Pursuant to Article 96(2) EPC

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Examiner:

Date Considered:

EXAMINER: Please initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



12-16-02

PCT

HDP/SB/21 based on PTO/SB/21 (08-00)

Please type a plus sign (+) inside this box → ☐

DT05 Rec'd PCT/PTO 13 DEC 2002

<b>TRANSMITTAL FORM</b> <i>(to be used for all correspondence after initial filing)</i>	Application Number	10/031,898	
	Filing Date	12/06/2000 (I.A.)	
	First Named Inventor	Kararli et al.	
	Group Art Unit	unknown	
	Examiner Name	unknown	
Total Number of Pages in This Submission		Attorney Docket Number	6794S-000005/USC

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ENCLOSURES (check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Response <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/ Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Assignment Papers (for an Application) <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition (1.47) <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): <b>Return Postcard References (6) Form PTO-1449</b>
Remarks		The Commissioner is hereby authorized to charge any additional fees that may be required under 37 CFR 1.16 or 1.17 to Deposit Account No. 08-0750. A duplicate copy of this sheet is enclosed.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm or Individual name	Harness, Dickey & Pierce, P.L.C.	Attorney Name Donald R. Holland	Reg. No. 35,197
Signature			
Date	December 13, 2002		

CERTIFICATE OF MAILING/TRANSMISSION			
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, or facsimile transmitted to the U.S. Patent and Trademark Office on the date indicated below.			
Typed or printed name	Mary Muir		
Signature		Date	12/13/2002

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